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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,694	10/20/2005	Daniel Fifer	PA1243	3897

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MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
3576 UNOCAL PLACE
SANTA ROSA, CA 95403

EXAMINER	
SHARMA, YASHITA	
ART UNIT	PAPER NUMBER
4177	

NOTIFICATION DATE	DELIVERY MODE
08/05/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary	Application No.	Applicant(s)	
	10/531,694	FIFER ET AL.	
	Examiner	Art Unit	
	YASHITA SHARMA	4177	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *14-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/18/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-13, drawn to a coated stent.

Group II, claim(s) 14-20, drawn to a method for producing a coated stent.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I claims features of a first eccentric portion on the stent inner diameter and a second eccentric portion disposed on the stent outer diameter that are not claimed in Group II. Group II claims steps of mixing a polymer and a therapeutic agent with a solvent to form a polymer/drug solution that are not claimed in Group I.

3. During a telephone conversation with Alan Krubiner on 07/24/2008, a provisional election was made without traverse to prosecute claims 1-13. Affirmation of this election must be made by applicant in replying to this Office action. Claims 14-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

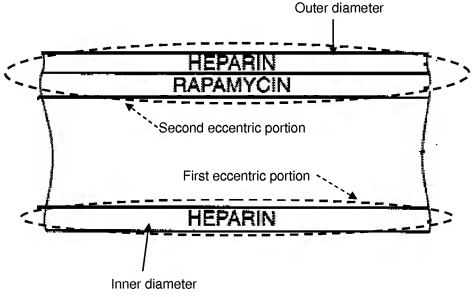
6. Claims 1, 2 and 4-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Falotico et al. (2003/0060877 A1).

7. Regarding claims 1 and 2, Falatico discloses a coated stent (pg. 13, par. 0133) (Fig. 8) comprising a stent 100 (Fig. 1), the stent having a stent inner diameter 110 (Fig. 8) and a stent outer diameter 114 (Fig. 8); and an eccentric coating ("heparin or rapamycin", 108 or 112) (Fig. 8), the eccentric coating having a first eccentric portion and a second eccentric portion (Object 1), the first eccentric portion disposed on the stent inner diameter and the second eccentric portion disposed on the stent outer diameter (Object 1); wherein the first eccentric portion and the second eccentric portion

have different thicknesses (the first eccentric or heparin coating portion has a different thickness on the inner surface than the second eccentric or heparin + rapamycin coating portion on the outer surface; with the coating overall being eccentric by virtue of the outer coating surfaces defining a central axis that is shifted relative to the band 102 of stent 100, pg. 13, par. 0133) (Fig. 8) . Furthermore, Falotico discloses the second eccentric portion is thicker than the first eccentric portion (as shown in Object 1).

8. Regarding claim 4, Falotico discloses the eccentric coating ("heparin or rapamycin", 108 or 112) (Fig. 8) includes a therapeutic agent (pg. 2, par. 0018).

Object 1
Fig. 8 of Falotico



9. Regarding claims 5 and 6, Falotico discloses a cap coating ("outer layer" pg. 8, par. 0087) disposed on the eccentric coating ("heparin or rapamycin", 108 or 112) (Fig.

8), the cap coating regulating elution of the therapeutic agent from the eccentric coating (the outer layer prevents rapamycin, containing therapeutic agents, from eluting too quickly, pg. 8, par. 0087).

10. Regarding claim 7, Falotico discloses a cap coating ("outer layer" pg. 8, par. 0087) is of substantially uniform thickness ("one micron to about twenty microns" pg. 8, par. 0087).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 3, 9-11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Falotico et al. (2003/0060877 A1) in view of Richter (6,315,794 B1).

15. Regarding claim 3, Falotico discloses the first eccentric portion and second eccentric portion (Object 1); except for the first eccentric portion is thicker than the second eccentric portion. However, Richter teaches a similar device wherein the stent 200 (Fig. 3A) is coated with a coating 102 (Fig. 3B) having a thickness that is optimized to provide desired properties (col. 5, lin. 18-20). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the device in Falotico to include a first eccentric portion having a thickness that is optimized to be thicker than the second eccentric portion, as taught and suggested by Richter, for the purpose of allowing the thickness to be varied depending on desired results and properties.

16. Regarding claim 9-11, Falotico discloses a cap coating ("outer layer" pg. 8, par. 0087), a first eccentric portion and a second eccentric portion (Object 1) and a second cap portion (the second cap portion is created by the cap coating disposed on the second eccentric portion or the outer diameter of the stent, as shown in object 1); except for the cap coating having a first cap portion disposed on the first eccentric portion, wherein the second cap portion is thicker than the first cap portion and the first

cap portion is thicker than the second cap portion. However, Richter teaches a similar device with a cap coating 102 (Fig. 3B) having a first cap portion disposed on the first eccentric portion (the first cap portion of cap coating 102 is disposed on the first eccentric portion or the inner diameter of the stent strut 110, Fig. 3B). Furthermore, Richter teaches the cap coating having a thickness that is optimized to provide desired properties (col. 5, lin. 18-20). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the cap coating in Falotico to have a first cap portion disposed on the first eccentric portion or the inner diameter, wherein the second cap portion is thicker than the first cap portion and the first cap portion is thicker than the second cap portion, as taught and suggested by Richter, for the purpose of disposing the cap coating, having varied thicknesses to produce desired results and properties, on the outer as well as the inner wall to allow diffusion of the therapeutic agent in the coating to the blood circulating inside the stent lumen.

17. Regarding claim 13, Falotico discloses the claimed invention in view of Richter; except for the first cap portion includes one therapeutic agent and the second cap portion includes a different therapeutic agent. However, Falotico does disclose two different therapeutic agents ("heparin" and "rapamycin", pg. 13, par. 0134) (Object 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the cap coating ("outer layer" pg. 8, par. 0087) in Falotico to have the first cap portion include one therapeutic agent, such as heparin, and the second cap portion includes a different therapeutic agent, such as rapamycin, for the purpose of using an anti-coagulant heparin on the inner diameter to prevent blood

clotting (pg. 13, par. 0129) and using a thrombosis inhibitor on the outer diameter to prevent restenosis of the smooth muscle tissue (pg. 2, par. 0018).

18. Claims 8 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Falotico et al. (2003/0060877 A1).

19. Regarding claim 8, Falotico discloses a cap coating ("outer layer" pg. 8, par. 0087); except for the cap coating includes a therapeutic agent. However, Falotico does disclose therapeutic agents in the coating compositions to prevent thrombosis. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the cap coating in Falatico to also include a therapeutic agent since it is the outer most layer, for the purpose of having a therapeutic agent in the outermost layer to prevent any thrombosis or restenosis of the smooth muscle tissue (pg. 2, par. 0018).

20. Regarding claim 12, Falotico discloses the second cap portion is biodegradable (the second cap portion of the cap coating ("outer layer" pg. 8, par. 0087) is created on the outer diameter of the stent where the coating is a biodegradable coating, pg. 2, par. 0018).

Conclusion

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to YASHITA SHARMA whose telephone number is (571)270-5417. The examiner can normally be reached on Monday - Thursday, 8 am to 4 pm EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Quang Thanh can be reached on 571-272-4982. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Quang D. Thanh/
Supervisory Patent Examiner, Art Unit 4177

/Y. S./
Examiner, Art Unit 4177